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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,690	02/04/2004	Kevin Ranucci	20563/2024	3949

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EXAMINER	
SHAHRESTANI, NASIR	
ART UNIT	PAPER NUMBER
3737	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,690	RANUCCI ET AL.	
	Examiner	Art Unit	
	Nasir Shahrestani	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/21/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

37 CFR 1.105 REQUIREMENT FOR INFORMATION

Applicant (or the assignee of this application if the assignee has undertaken the prosecution of the application) is required under 37 CFR 1.1.05 to provide the following information that the examiner has determined reasonably necessary to the examination of this application.

There are numerous other co-pending application and issued patents, which disclose and claim very similar and/or identical subject matter. In accordance with 37 CFR 1.105 and MPEP 704.11(a) subsection G, applicant (or the assignee) is respectfully requested to disclose all co-pending application and related patents (please see the non-exhaustive list below of applications

and issued patents that the USPTO believes may be related) and identify the specific claims of those applications and/or patents which may present double patenting issues with the instant application claims. This requirement is reasonably necessary to examination because, based on an initial review of the applications, there is a significant degree of overlap in claimed subject matter, thus requiring an analysis of commonality of claimed subject matter to determine patentability under 35 USC 101 double patenting and/or obviousness type double patenting. For example,

Claims 1-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,695,782. Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent obvious alternate variations and groupings of the patented claims.

Claims 1-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12, 14-32, 64-70, 72-75 of copending application No. 10/774,985. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are broader and are therefore anticipated by the conflicting claims. The instant claims are broader in that they do not include the steps of the probe being propagated in backward and forward directions and delivering a specific range of ultrasonic frequency as described in claim 12 of copending application No. 10/774985.

Because the applicant (or the assignee) is presumably far more cognizant of the contents of the claims in these applications than any Office staff, and has access to the source documents by which such comparison could be done better than within the Office, it is reasonable to require

the applicant to provide the information needed to determine the commonality •among the claims.

Should applicant (or the assignee) believe that Double Patenting exists, then applicant (or the assignee) is invited to file Terminal Disclaimers and/or amend the currently pending claims in the interest of expediting the prosecution of the current application. Applicant (or the assignee•) should note that a terminal disclaimer is effective to overcome an obviousness type double patenting rejection, but will not overcome a "same type" double patenting rejection under 35 U.S.C. § 101.

Non-exhaustive list of possible but not limited related co-pending applications and patents:

US 6,695,782	2005/0187514
US 6,695,781	2006/0100547
US 6,679,873	2005/0267488
US 6,802,835	2005/0187514

This requirement is subject to the provisions of 37 CFR 1.134, 1.135 and 1.136 and has a shortened statutory period of 2 months. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Karen M. Young

KAREN M. YOUNG
DIRECTOR
TECHNOLOGY CENTER 3700

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 13, 17-29, are rejected under 35 U.S.C. 102(b) as being anticipated by Sakurai et al. (U.S. 5,391,144).

Regarding claim 1, Sakurai et al. teaches an ultrasonic device for removing occlusions in blood vessels (col. 1 lines 12-53) comprising: an ultrasonic probe having a proximal end and a distal end (fig. 13, alternative ultrasound probes 61 and 62, both having a proximal end and a distal end); a horn assembly (element 63) having a proximal end and a distal end which is engaged to the proximal end through a coupling assembly (horn element 63 transmits the vibrations to the ultrasonic probes through attachment means (elements 73a & 73b); wherein the coupling assembly (elements 73a & 73b) transmits an ultrasound energy from the horn assembly to the ultrasonic probe (col. 12 lines 45-68; col. 13 lines 1-6).

Regarding claims 2-3, Sakurai et al. teaches wherein the horn assembly amplifies the ultrasound energy (col. 13 lines 7-15), after which a portion of the generated signal is reflected back into the horn assembly.

Regarding claims 4-5, 7-8, Sakurai et al. further teaches a sound conductor with a proximal end and a distal end, said distal end being connected to the coupling assembly and said

proximal end being connected to a transducer capable providing ultrasound energy (see Figure 13, element 63; and also see col. 12, lines 45-68 and col. 13, lines 1-6), wherein said probe is releasably mounted at its proximal end to said probe attachment means, enabling said sound conductor to transmit ultrasound energy from said transducer to said probe, causing said probe to be oscillated in a substantially transverse mode to the probe longitudinal axis and wherein the probe is capable of supporting standing transverse sound waves to cause generation of ultrasonic cavitation energy in at least one location along the longitudinal axis of the ultrasonic probe (in Figure 13, see how the horn (element 63) transmits the vibrations to the ultrasonic probes (elements 61 or 62), through the attachment means (elements 73a and 73b); regarding the transverse oscillation of the probe see Figures 40 and 41 and indications of anti-node or loops wherein there is maximum oscillation along the length of the probes) and wherein the sound conductor and transducer (vibrating at an ultrasonic frequency) are in the device handle as illustrated by fig. 13. Furthermore since the horn assembly acts to amplify the ultrasound signal, storage of an amount of energy is an inherent feature of such a device.

Regarding claim 6, Sakurai et al. teaches wherein the coupling assembly presents an impedance mismatch between the horn assembly and the ultrasonic probe (col. 8 lines 1-19; col. 9 lines 20-68; col. 10 lines 1-30).

Regarding claim 13; Sakurai et al. teaches wherein a locking nut engages the horn assembly to the ultrasonic probe by engaging screw threads of licking nut and complimentary threads on the horn assembly (col. 13 lines 1-6).

Regarding claim 17, Sakurai et al. teaches all the limitations as described above in rejection of claims 1, 2, and 4 above.

Regarding claims 18-25, Sakurai et al. teaches all the limitations as described above in rejection of claims 5, 6, 8, 12, 13, & 10.

Regarding claim 26-29, Sakurai et al. teaches a method of ablation (col. 1 lines 12-53) comprising: inserting an ultrasonic probe into the vessel (figs. 30, 31); moving the ultrasonic probe within the vessel to a site of the endovascular material and engaging a horn assembly (col. 13 lines 7-15) to amplify said ultrasonic energy causing said probe to be oscillated in a substantially transverse mode to the probe longitudinal axis and wherein the probe is capable of supporting standing transverse sound waves to cause generation of ultrasonic cavitation energy in at least one location along the longitudinal axis of the ultrasonic probe (in Figure 13, see how the horn (element 63) transmits the vibrations to the ultrasonic probes (elements 61 or 62), through the attachment means (elements 73a and 73b); regarding the transverse oscillation of the probe see Figures 40 and 41 and indications of anti-node or loops wherein there is maximum oscillation along the length of the probes) and wherein the sound conductor and transducer (vibrating at an ultrasonic frequency) are in the device handle as illustrated by fig. 13. Furthermore since the horn assembly acts to amplify the ultrasound signal, storage of an amount of energy is an inherent feature of such a device. Sakurai et al. also teaches wherein a locking nut engages the horn assembly to the ultrasonic probe by engaging screw threads of locking nut and complimentary threads on the horn assembly (col. 13 lines 1-6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-16, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakurai et al. (U.S. 5,391,144) in view of Levin et al. (U.S. 5,971,949).

Sakurai et al. teaches a guide catheter for introduction of tools (see col. 19, lines 48-50; describing a tool-guiding channel), but does not specifically teach a device wherein the ultrasonic probe is a flexible elongated guide wire or wherein the ultrasonic probe is a catheter guide wire. In the same field of endeavor, Levin et al. teaches a device wherein the ultrasonic probe is a flexible elongated guide wire or wherein the ultrasonic probe is a catheter guide wire or wherein the guide wire is a vascular guide wire (see col. 2, lines 3-6 and col. 5, lines 38-60). It would have been obvious to one skilled in the art at the time that the invention was made to have modified Sakurai et al. and incorporated the teaching of Levin et al. to incorporate a guide wire as an ultrasonic probe being introduced within a catheter sheath if the procedure of interest was treatment of intravascular blockage and therefore as an alternative to the probes depicted in Figure 13, mainly ultrasonic probes 61 and 62 in Sakurai et al. (Levin et al. describes use of the guide wire within a catheter adapted for coupling to an ultrasound transmission device to break up blockage intra-vascularly by forming a longitudinal standing wave (see col. 19, lines 47-54)).

Claims 9-12, 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakurai et al. (U.S. 5,391,144) in view of Levin et al. (U.S. 5,971,949) and in further view of Unflacker et al. (U.S. 5,524,635).

Sakurai et al. in view of Levin et al. teaches all the features of the instant invention including a coupling assembly connecting an ultrasonic source with an ultrasonic catheter with a guide wire. However they do not teach the coupling assembly comprising a releasable compressive clamp mounted externally to a collet residing in a housing assembly at the distal end of the coupling assembly, the collet being capable of releasably engaging the ultrasonic probe. In the same field of endeavor, Unflacker et al. teaches a handle having a vibrating device attached to a guide wire with a releasable collet (see col. 4, lines 19-64). It would have been obvious to one skilled in the art at the time that the invention was made to have modified Sakurai et al. in view of Levin et al. and substituted for the handle device set up of the catheter guide wire with the releasable collet, wherein the vibrating device would be made of ultrasonic transducers, as an alternative operator handle of controlling the guide wire/catheter system. While Unflacker et al. does not specifically enumerate the use of a clamp, its use would be an obvious alternative functional equivalent to a skilled artisan at the time that the invention was made, as a well-known means for providing for a releasable guide wire that exhibits flexibility so that not to damage the vessel.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nasir Shahrestani whose telephone number is 571-270-1031. The examiner can normally be reached on Mon.-Thurs: 7:30-5:00, 2nd Friday: 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NS/
Nasir Shahrestani
3/09/2007

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